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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,481	06/20/2001	Takao Hamakubo	P21128	9557

7055 7590 08/13/2003

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EXAMINER

FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,481

Applicant(s)

HAMAKUBO ET AL.

Examiner

Shanon Foley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

In paper no. 9, applicant amended claims 1, 9 and 12. Claims 1-14 are pending in the application, claims 9-14 are withdrawn from consideration due to non-elected subject matter and claims 1-8 are under consideration.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 10/22/01 is being considered by the examiner. A signed and initialed copy of the PTO-1449 applicant has supplied with the response is hereby forwarded to applicant.

Drawings

Applicant notes that the Office did not forward a PTO-948 with the last Office correspondence and presumes that the drawings submitted with the application are in compliance.

Applicant is correct. The drawings filed with the instant application are acceptable by the examiner.

Election/Restrictions

Applicant requests the examiner to consider each of the proteins as species to be rejoined upon indication of allowable subject matter. Applicant also requests that the restriction requirement should be reconsidered and withdrawn for the previously submitted reasons. In the case that the restriction is not withdrawn, applicant also requests rejoinder of the other groups upon indication of allowable subject matter.

Applicant's requests have been fully considered, but are unpersuasive.

The proteins listed in each of the claims are patentably distinct and are not considered species of one another because they are unrelated. MPEP § 806.04, MPEP § 808.01 state that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. In the instant case, each of the proteins differ in sequence structure, three dimensional structure, chemical composition, and have a wide distribution among cell types and divergent function. Therefore, the proteins in the claims are not species, but are unrelated and are patentably distinct.

The request for withdrawal of the restriction requirement has been reconsidered, but is found unpersuasive. The burden of searching for each of the distinct inventions is established by an explanation and reasons for how each invention is independent and distinct. A serious search burden is also established by the fact that each invention is categorized into separate classifications in the art, indicating divergent subject matter.

The request for a rejoinder of the other groups upon indication of allowable subject matter has been considered, but is found unpersuasive. In accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. However, applicant did not elect a product claim to be examined. Therefore, applicant is not entitled to a rejoinder.

This application contains claims 9-14, drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bandman et al. (US 5,858,750) for reasons of record.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ikeda et al. (PNAS. 1995; 92: 126-130) for reasons of record.

Applicant argues that neither Bandman or Ikeda teach or suggest that the protein is expressed in a budded baculovirus released from the host because the proteins within the references are expressed in the host cell or in culture solution. Applicant points to specific passages in Bandman, which indicates that retinol dehydrogenase is a membrane-bound enzyme, but argues that Bandman does not teach expression of the protein from the virus.

Applicant also argues that Ikeda teach that the protein is secreted into the supernatant of culture as a soluble protein, which is different from the instant invention where the protein is expressed in a budded baculovirus. Applicant argues that Ikeda does not refer to virus particles in the supernatant. Applicant also argues that the protein of Ikeda lacks the membrane anchor domain and is no longer a membrane protein.

Applicant concludes that each of the dependent claims are patentable over the prior art because the combination of features within the claims is not taught in the prior art and that it would not have been obvious for the ordinary artisan to arrive at the invention.

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In response, it is not clear why applicant is arguing obviousness when the claims are anticipated by the prior art.

Applicant's arguments have been fully considered, but are found unpersuasive. As discussed in the previous Office action, Bandman et al. teach a method of producing a membrane enzyme, human retinol dehydrogenase type II homolog (HRoDH), by culturing a host cell and recovering the enzyme from the host cell culture. The host cell is an insect cell baculovirus system. See claim 8 and column 1, lines 53-56, column 14, lines 6-12 and 29-30. Therefore, the instant invention is clearly anticipated by Bandman et al.

In the response on page 9, applicant discusses the natural life cycle of the baculovirus, which includes budding from the host cell, rupturing the cell membrane and being released outside the cell. The natural life cycle of the baculovirus is unaltered in the teachings of Ikeda or Bandman. Therefore, the recombinant baculovirus expressing each of the membrane-bound enzymes of Bandman or Ikeda buds from the host cell, ruptures the cell membrane and is released outside the cell.

Contrary to applicant's assertions, Ikeda does refer to recombinant baculovirus particles in the supernatant, see "Generation of Recombinant Baculovirus" on page 126. Ikeda Applicant also teaches expressing the wild-type human γ -glutamyl transpeptidase and a mutant in the baculovirus system, see "Generation of Recombinant Baculovirus" on page 126.

Therefore, all of the limitations are anticipated by Bandman or Ikeda.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Shanon Foley
August 9, 2003


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-160